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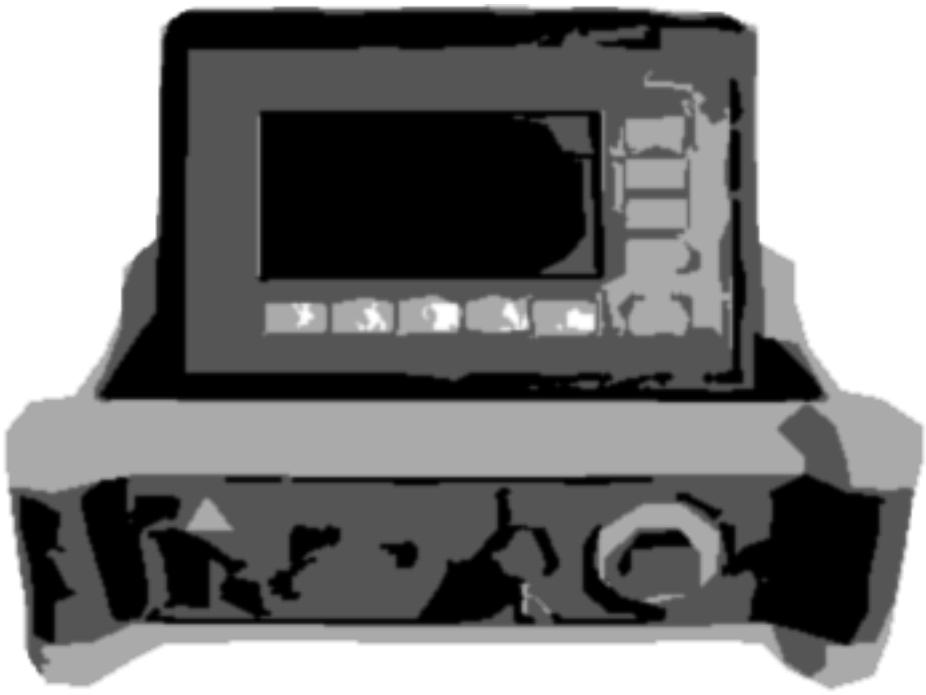

MDL-10 Dental Laser Unit

USER MANUAL

IMPORTANT !

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Users of VISION LASERTECHNIK GmbH products should not hesitate to point out to us any errors or unclarities in this manual.

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⚠ Important Note

Read this manual
Read this user manual thoroughly and familiarize yourself with the use and functioning of the device and all accessories prior to using the device in the operating room. Failure to follow these instructions may result in:

- Serious injury to the patient
- Serious injury to the operating team or service personnel, or
- Damage to or a malfunction of the device or accessories.

Modification
The manufacturer reserves the right to modify the appearance and technical performance of the product through continued development of the production of the product.
Please read this manual completely and follow its instructions carefully. The sections labelled WARNING, CAUTION and NOTE contain important information. Read these sections carefully.

⚠ WARNING or DANGER

The safety of the patient, the operating team or a third party is a risk. Disregarding this information could result in injury to the patient.

⚠ CAUTION

These instructions point out special service procedures or precautions that must be followed to avoid damaging the device.

⚠ NOTE

This provides special information that facilitates maintenance of clarifies important instructions.

CE$_{0482}$ / MED/CERT

CE marking according to Directive 93/42/EEC

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1. Safety Instructions

Warranty

The manufacturer warrants that the device and the accessories will be free from manufacturing and material defects for one (1) year from initial operation. The warranty is limited to the terms and conditions described herein, and there are no other warranties, expressed or implied.

No Liability

The manufacturer shall not be liable for direct or incidental damage, and the warranty shall become void if:

- The device or the accessories are improperly used;
- The instructions and rules in the manual are not adhered to;
- The device or the accessories are improperly prepared or serviced;
- Unauthorized persons perform repairs, adjustments or alterations on the device or accessories;
- An unauthorized person perform repairs, adjustments or alterations on the device or accessories;
- The prescribed inspection and maintenance schedule is not adhered to.

Authorized Service Technician

Only an authorized service technician may perform repairs, adjustments, or alterations on the device or accessories.

Care

To guarantee safe operation, it is absolutely necessary to carry out proper care of the device and accessories. For the protection of the patient and the operating team, verify that the device is complete and functional before each use.

New products, as well as repaired products, must be prepared and tested according to the manual instructions prior to use.

1.1. Warnings

Water hazard: Protect the device from being splashed by water. Keep the key switch dry. Should any liquid enter the device, discontinue use immediately.
Original accessories: For your own safety, and that of your patient, use only original accessories.
Internal standard settings: Check all settings that are standard to your work place. Such internal standard settings are not necessarily prescribed for the doctors. The physician is responsible for all settings required for his or her operation.
Specific Technique and Procedures: Only the physician can evaluate the clinical factors involved with each patient and determine if the use is indicated. The physician must determine the specific technique and procedure that will accomplish the desired clinical effect.
Available Voltage: Determine if the available voltage corresponds to your device. Working with wrong voltage will cause the device to malfunction or may permanently damage the device.
Not Explosion-proof: Electrical components are not explosion-proof. Do not use in an area where flammable gases are present.
Risk of Electrical Shock: To reduce the risk of electrical shock, do not remove cover (or back). Refer servicing to qualified service personnel.
Professional Qualification: This manual does not provide a detailed description of operation techniques, nor is it suitable for introducing a beginner to this operating technique. Medical accessories and devices may be used only by physicians and medical assistants under the directive of a physician with the appropriate professional qualification.
Function Test: A function test must be performed prior to each operation.
Sterile Substances and Accessories: Always work exclusively with sterile substances and sterile accessories.
Cleaning the device: Do not sterilize the device.
Replacement fiber: A replacement fiber should be kept in the immediate vicinity to allow the surgeon to complete the procedure in case of fiber damage.
Specific Device Warnings: Read the specific warnings for this device in Chapter 2 Purpose of the Device.
Defect: If a defect is suspected or confirmed, stop using the device until it has been checked by authorized service personnel. This also applies if the device fails to maintain the indicated tolerance levels.
Endoscope: The device may only be connected to endoscopes designed for the use with the device for the intended medical procedure. The endoscopes must comply with the most recent versions of IEC 601-2-18 and ISO 8600.
Servicing and Adjusting: Do not open the device. The device must not be serviced or adjusted by the user. Only authorized technicians may perform repairs, adjustments or alterations to the device or to its accessories.
Exposure to Hazardous Radiation: Use of controls or adjustments or performance of procedures other than those specified herein mnay result in exposure to hazardous radiation.

2. Purpose of the Device

2.1. Intended Use

The VISION laser MDL-10 is a diode laser (GaAl) with a wavelength of 980 nm. This laser radiation is suitable for cutting or coagulating soft tissue as well as for activating photochemical processes (Bleaching). If the laser radiation is used at very low energy densities it is suitable for therapeutic applications.

Indications for Use

The VISION laser MDL-10 is a surgical laser device for use in soft tissue treatment in dentistry, e.n.t., and other medical applications.

Contraindications

The laser beam (end of the fiber) should not be used on mineralised tissues like enamel, dentine or bones to avoid damages by overheating.

2.2. Mechanism of Action

The laser beam produced by the VISION laser unit MDL-10 emits pulses with a repetition rate from 1 to 1000 pulses per second. This repletion rate is adjustable. The laser beam is transferred to the point of action through the laser fiber, exiting the distal end of the fiber as a divergent beam. The laser energy will be transformed into heat, which will interact with the desired tissue by cutting or coagulating or by activating of chemical substances or in case of very low energy densities by photon activated therapeutic interactions.

2.3. Laser Radiation, Safety Regulations, Laser Class

Laser Radiation: The VISION laser device MDL-10 produces laser radiation. Laser radiation is defined as electromagnetic radiation in the wavelength range from 100 nm to 1 mm in the form of controlled, stimulated emission. The VISION laser device MDL-10 produces laser radiation with a wavelength of 980 nm by stimulated emission of a electrical excited GaAl – diode.

Safety Regulations: All safety precautions according to IEC 825 ("Radiation Safety for Laser Equipment") must be observed to protect the patient and the user. Before using the VISION laser device MDL-10, the patient must be informed of the mode of operation of the application. The VISION laser device MDL-10 is a Class 4 laser device.

Laser Class: Class 4 means that direct as well as diffuse indirect radiation can be dangerous to skin and eyes. Proper use of the device, however, has a healing affect to the patient if the use of the radiation is targeted. Nonetheless, uncontrolled emission of radiation can be dangerous and this requires that appropriate safety measures be taken.

2.4. Aiming Beam

An aiming beam is incorporated within the device to direct the fiber to its target and to control the fiber quality. This beam is visible at the distal end of the fiber as a red light (wavelength 635 nm, hazard class of laser 3B) and is harmless.

WARNING

Never look directly into the end of the fiber laser (aiming beam and/or treatment beam) while the laser is activated ! This can cause damage to the retina !

CAUTION

The laser must not be operated if the aiming beam is not visible

---

The total laser radiation output always includes the aiming beam. For definition purposes, the portion of the laser radiation used to tissue interaction with its wavelength of 980 nm, is identified as "treatment beam".

If the aiming beam is not visible prior or during the operation, the laser treatment must be aborted.

2.5. Laser Area

The laser area in the context of the above regulations is identified as the enclosed space in which the VISION laser device MDL-10 is set up to used and which is separated from other spaces by means of solid walls and doors. Ensure that the laser area contains no highly reflective surfaces such as mirrors.

The use must identify the laser area as such. This is to be done by posting laser warning signs "WARNING – LASER RADIATION" according to IEC 825. Signs are commonly available throughout the industry and can also be obtained from VISION upon request. A hazard sign is included with these instructions.

At all entrances of the laser area, care must be taken so that no person is exposed to laser radiation by inadvertently entering the area. For this purpose, laser warning lamps must be located outside of the entrances to the laser area to indicate the laser is in operation. Door switches may be used to ensure the laser is switched off in case of unauthorized entry.

All existing entrances and windows should be fitted with protective laser curtains. An equivalent degree of safety may be achieved by using laser radiation curtains.

2.6. Instructions to Personnel and Notification of Laser Operation

Observe applicable national guidelines regarding:

- Instructing personnel in laser operating
- Registering laser operation with public authorities
- Documenting maintenance intervals
- Emergency shut off the laser

Verify that all applicable regulations have been observed before operating the unit.

⚠ **CAUTION**

The respective public authorities should be informed of plans to operate laser equipment prior to initial operation of the laser

---

2.7. Protective Laser Goggles, Protective Clothing

⚠ **WARNING**

All persons in the laser area, including the patient, must always wear protective laser goggles to avoid eye injury. Failure to wear protective laser goggles can result in severe injury to the eyes including blindness 1

⚠ **WARNING**

Never look directly into the end of the fiber laser (aiming beam and/or treatment beam) while the laser is activated ! This can cause damage to the retina !

Since the intensity of the laser radiation exceeds the maximum permissible limit for radiation, all persons within the laser area must wear appropriate laser protective eyewear and clothing to protect their eyes and skin. The operator must provide appropriate protection.
Protective eyewear for the laser radiation at 980 nm must be identified as protective laser goggles according to ANSI Z136.1. The protective eyewear in use must have an 980/L4 degree of protection that corresponds to the intensity and type of laser radiation emitted from the VISION laser device MDL-10.

Always wear protective laser goggles when preparing the fiber. This prevents possible eye injuries from fiber splinters.
Protective laser goggles are available from VISION. Any sturdy clothing can be used as protective clothing.

2.8. Miscellaneous Hazard Instructions

The area at which the laser is emitted, i.e. the distal end of the fiber, has a very high radiation energy and power density. Up to approximately 1 cm in front of the fiber exit surface, the laser radiation energy density is very high and can ignite easily flammable materials. Therefore, the irradiation of flammable material must be avoided.

2.9. Laser Fiber

To ensure perfect function and to guarantee laser safety, only laser fibers that have been approved by VISION may be used. AN important factor in the safe application of the laser radiation in the area of intended use is the optical quality of the fiber transmission. This system consists of the fiber plug and the optical fiber. Only original parts guarantee safe beam guidance within the fiber and correct beam characteristics at the distal end of the fiber.
Incorrect fibers, incorrectly operated devices or broken fibers endanger the patient and personnel and must never be used.

DANGER

Using a fiber other than the specified fiber can result in dangerous radiation exposure.

2.10. Labelling the Laser

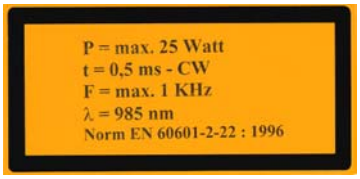
The VISION laser device MDL-10 is supplied with warning and information signs.

Label No. 1
Label on the front of the laser

Label No. 2
Label on the rear of the laser

Unsichtbare Laserstrahlung
Bestrahlung von Auge oder Haut durch direkte oder Streustrahlung vermeiden
Laser Klasse 4

Label No. 3
Label on the rear of the laser:



Label No. 4
Label on the rear of the laser:

3. Initial Operation

Initial Inspection

Check the device and all accessories immediately upon receipt to make sure contents are complete and nothing is damaged.

Returning the Device

If it becomes necessary to return the device, the original packaging must be used. The manufacturer shall assume no responsibility for damage that has occurred during shipping if the damage was caused by inadequate shipping packaging.

Please enclose the following information with the device:

- Owners name
- Owners address
- Type
- Serial number of the equipment (see identification plate)
- Description of the damage

Setting up the Device

Place the device on a horizontal surface in a dry place. The ambient temperature should be between 18 – 30 °C (64 – 86 °F), and the relative air humidity should be between 30 – 75 %.

WARNING

The electrical components are not explosion-proof. Do not use in an area where flammable gases are present.

Power supply connection

CAUTION

Determine if the available voltage corresponds to your device. Working with the wrong voltage will cause the device to malfunction or may permanently damage the device.

The specifications of the main power supply must comply with IEC, CEC and NEC requirements.
Ensure that the key switch is in the OFF position (vertical position).

Safety Plug

The power supply cable must be equipped with a safety plug. Use the enclosed power cable for the connection between the power plug and the device socket.

The power plug must be connected to a 220 – 240 V ac protected contact receptacle with at least 2 A fuse.

Potential Equalization

The equalize potential differences, the VISION laser device MDL-10 can be connected from the grounding screws at the rear of the device to the ground-protected receptacle in the treatment room using a common grounding cable in accordance with the local safety regulations.

Ventilation Openings

At the sides of the laser, the housing has air inlet and outlet openings allowing for air exchange to cool the device. During operation, care must be taken not to block or hang anything over the at openings.
A 20 cm gap must be maintained to ensure proper cooling function.

3.1. Installation

Prior to operation, verify that the room in which the device is to be set up is free of materials that can result in electrostatic charge build-up, such as carpeting.

The initial installation of the VISION laser device MDL-10 is performed by VISION or by a dealer authorized by VISION. Here, an initial operation record will be filled out. A copy of the initial operation record, signed by the manufacturers representative and a person authorized by the customer accepting the laser remains with the customer. At the same time, one or more designated persons will be trained in the operation of the system; their names are entered into the training log.

CAUTION

All work on and in the device that is not part of regular operation must be performed by VISION technicians or persons authorized by VISION only.

External Door Contact

The VISION laser device MDL-10 has a connection on the rear for a remote safety interlock according to IEC 825 § 4.4. Opening contacts 1 and 5 in the jack will cause the system to automatically shut down. A break contact can be connected between these contacts, which is opened by the entrance door to the laser area.

However, it is not recommended that door contacts be connected since when the door is opened, the laser will immediately shut down and treatment will be interrupted. The system is shipped with a shorting plug for this reason. The decision to connect the door contact is to be made by the users safety representative. It is recommended that this issue be discussed with the appropriate supervisory authorities.

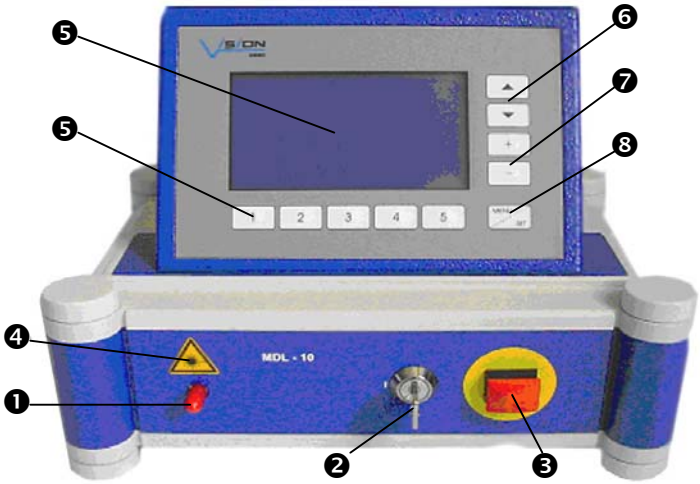
Initial Operation

After all safety precautions have been checked out and the device has been installed, the VISION laser device MDL-10 can be turned on.

The laser unit is adjusted at the factory. Therefore you should follow the same procedure during initial operation as in normal operation (see Chapter 4).

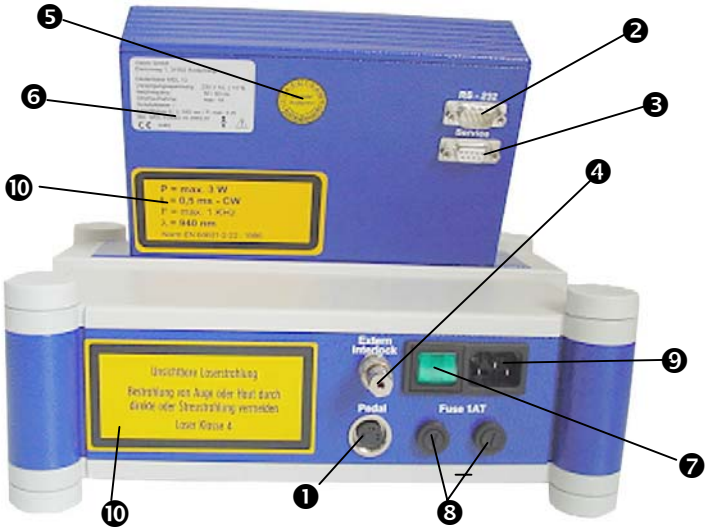
4. Operating the Device

4.1 Front of the device



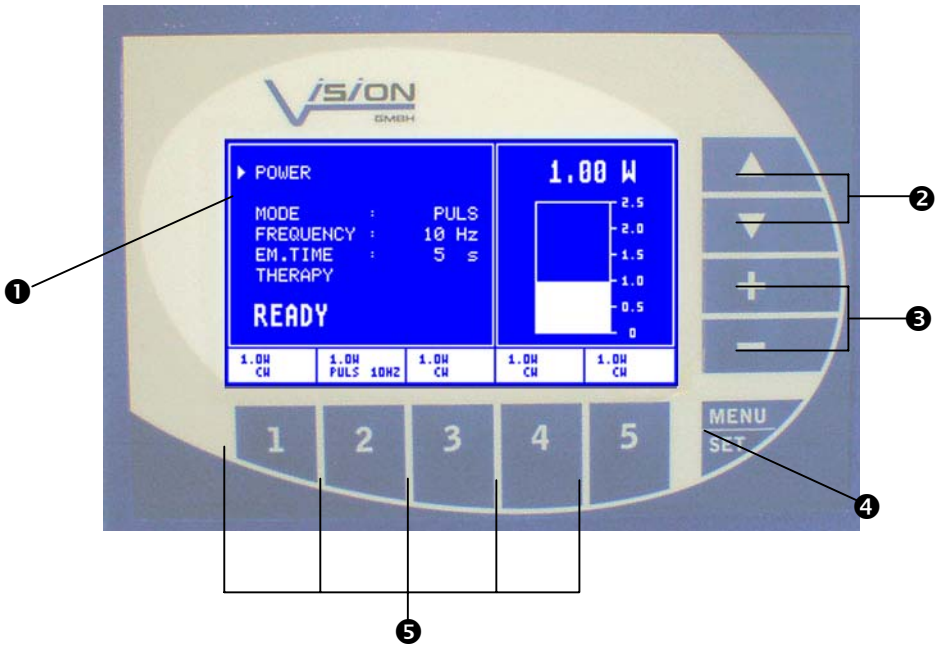
❶ fiber connection
❷ key switch
❸ emergency stop
❹ laser sign
❺ operator panel
❻ change of programs
❼ parameter setting
❽ Ready / Standby

4.2. Rear of the device



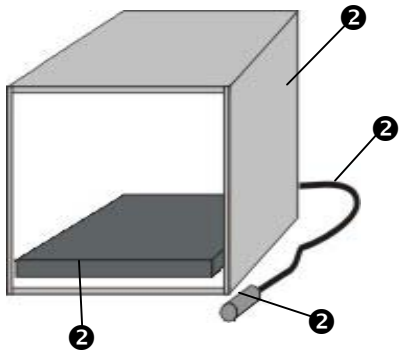
❶ foot switch connection
❷ RS232 - interface
❸ SERVICE interface
❹ external door contact
❺ sign for yearly check up
❻ identification plate
❼ mains switch
❽ mains fuses 2 x 2 A mT
❾ mains socket
❿ laser label

4.3 Operator Panel



❶ operation information screen
❷ up / down for program
❸ + / - change of parameters
❹ MENU / SET – Ready / Standby
accept changes in parameter
❺ program 1 – 5, individual

4.4. Foot Switch



The VISION laser device MDL-10 is operated using a foot switch. The foot switch consists of the actual foot contact (1) and the securely connected feed cable (2) with locking plug connection (3). The foot contact is covered by a hood (4) to keep it from being stepped on inadvertently.

Attaching the foot-switch

1. Connect the foot-switch plug to the foot switch connection at the rear of the device.
2. Screw on the foot switch plug securely

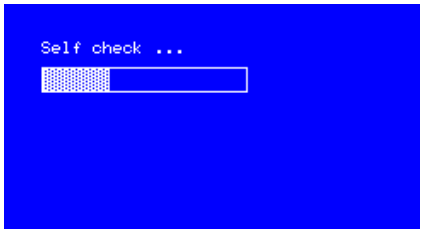
4.5 Start-Up

1. Connect the mains plug to a suitable power supply.
2. The emergency STOP switch is then unlocked by pulling the red cap.
3. Insert the key and turn on the device by turning the key to the right by 90°

   -- check if interlock connector or external interlock circuit is activated --

The device will start with an introduction screen of VISION

The laser device is now ready to operate, and the device will perform an internal system test lasting approximately 5 seconds.

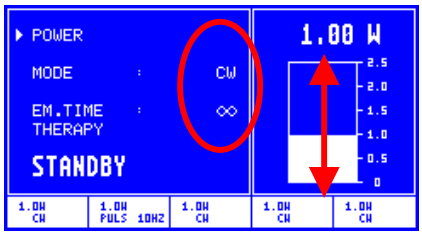


After successful self testing the laser is ready for use.

4.6. Setting of Mode and Parameters

4.6.1. cw-Mode

with the up/down buttons choose the cw mode, which is mostly used for surgery. *CW means continues wave, the laser is emitting always as long it is activated, indicated by the EM.TIME with an indefinite sign (∞) in the display.*

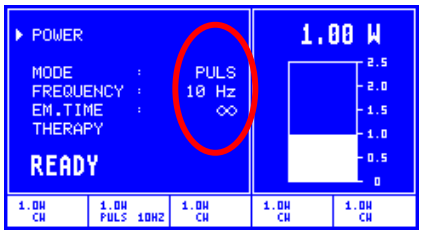


Use the MENU/SET button to confirm.

In the cw-mode the power can be changed from 0,0 up to 2,5 watts by using the + / - buttons.

4.6.2. pulsed-Mode

with the up/down buttons choose the pulse mode, which is used in periodontology and endodontology. *Pulse means that the laser is switched on and off in a indicated frequency, (here 10 Hz).*

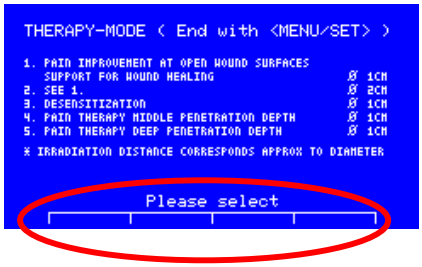


Use the MENU/SET button to confirm.

In the pulse-mode the power can also be changed from 0,0 up to 2,5 watts by using the + / - buttons.

4.6.3. Therapy-Mode

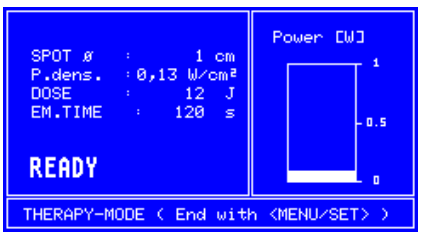
with the up/down buttons choose the therapy mode, which is used in various applications, where the laser light should stimulate. In this mode the laser energy is very low, far from power level to cut or coagulate.


THERAPY-MODE (End with <MENU/SET>)
1. PAIN IMPROVEMENT AT OPEN WOUND SURFACES
SUPPORT FOR WOUND HEALING Ø 1CM
2. SEE 1. Ø 2CM
3. DESENSITIZATION Ø 1CM
4. PAIN THERAPY MIDDLE PENETRATION DEPTH Ø 1CM
5. PAIN THERAPY DEEP PENETRATION DEPTH Ø 1CM
* IRRADIATION DISTANCE CORRESPONDS APPROX TO DIAMETER
Please select

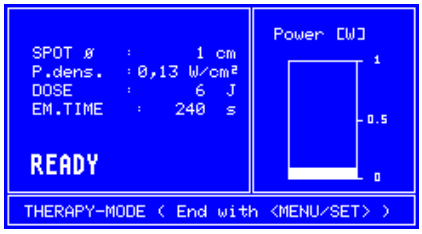
Use the MENU/SET button to confirm.

In the therapy-mode the 5 pre-selected application have been already implemented and can be chosen by the 5 program buttons.

i.e.



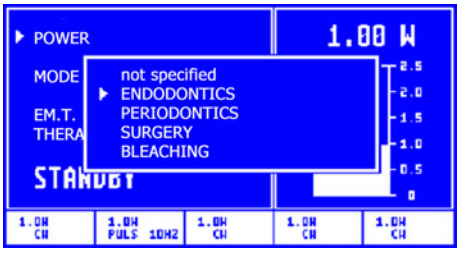
Therapy-Program 1:
Pain treatment at open wound surfaces support for wound healing
Spot size: 1 cm
Power density: 0,13 W/cm^2
Dose: 12 J
Emission Time: 120 s



Therapy-Program 2:
desensitisation
Spot size: 1 cm
Power density: 0,13 J/cm^2
Dose: 6 J
Emission Time: 240 s

4.6.4. Pre-selection and storage of application programs

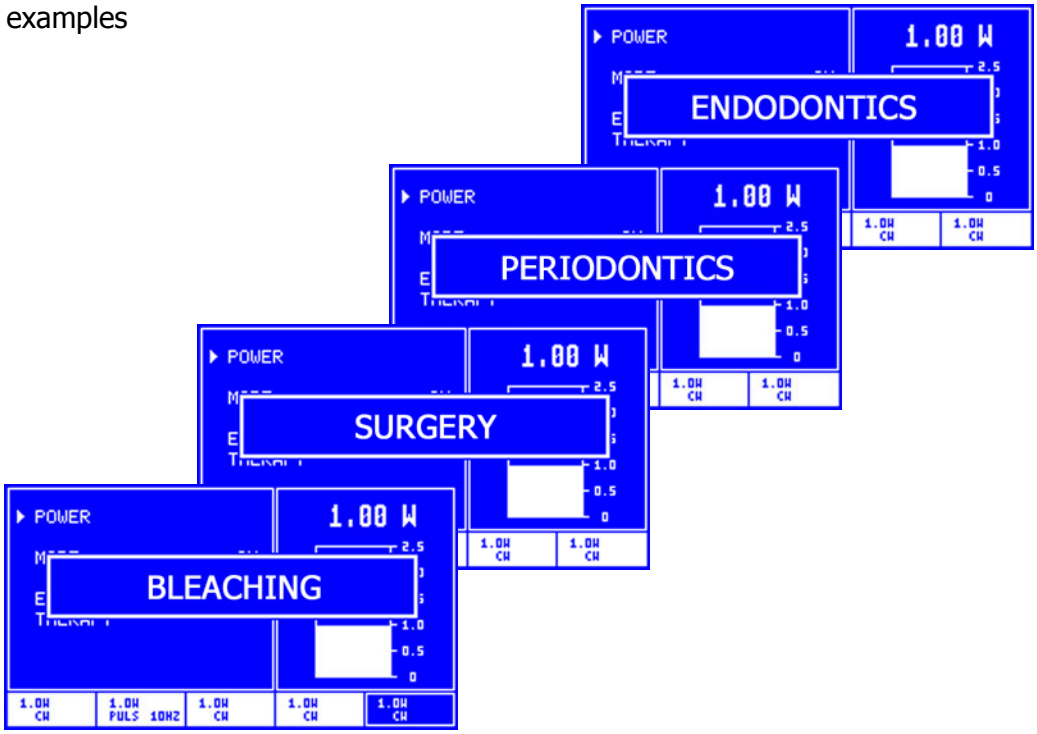
The VISION MDL devices allow to store parameters for different applications for easier access by the operator. This will be performed by using the memory keys at the lower rim of the user screen.
→ Press one of the 5 buttons for at least 3 seconds – and a selection menu will appear.
→ Choose one of the shown indications by using the up / down keys and press the menu / set button to store the parameters.



The following applications are suggested:

- ENDODONTICS
- PERIODONTICS
- SURGERY
- BLEACHING

examples



Each time one of the application is activated by using the specified key button, the application will be highlighted on the screen for some seconds.

4.7. All Parameters

The user can select and change all the programs and parameters by up/down and +/- buttons, always confirmed by MENU/SET button:

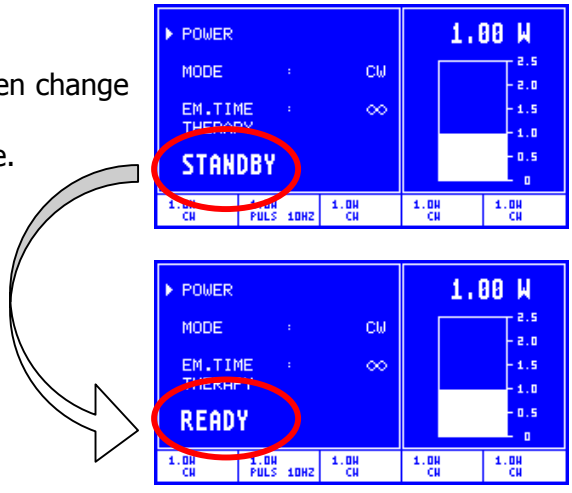
POWER:	1 – 2,5 Watts
MODE:	cw or pulsed Option – extra oral 1 = pulsed mode with free selectable pulse length and pulse repetition rate Option – extra oral 2 = pulsed mode with selectable pulse length and pulse pause
REPETITION RATE:	10 – 1000 Hz in pulsed mode
PULSE LENGTH:	1 ms – 1000 ms
PULSE PAUSE:	1 ms – 1000 ms or 1 pulse
EMISSION TIME:	pre-selected changeable emission from 1 – 60 s
THERAPY MODE:	select from 5 preset programs

4.8. STANDBY / READY

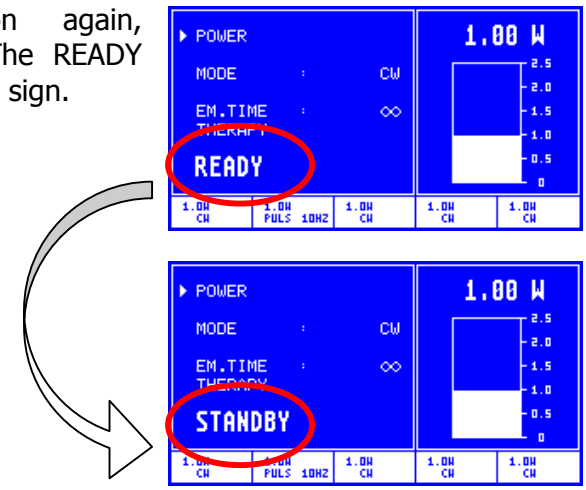
The "ready-to-fire" state of the laser can only be enabled once all persons within the laser area are wearing their protective laser goggles and the warning lamp at the entrance to the laser area is turned on.

Push the MENU / SET button:

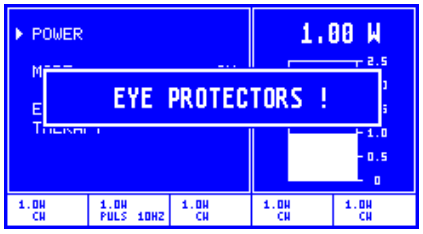
1. the word STANDBY in the screen change to the word READY.
2. the laser device is ready for use.



Pushing the MENU/SET button again, deactivates the treatment beam. The READY sign will be replaced by the STANDBY sign.



If the laser is not used for an extended time (>90 s), it deactivates automatically.



A message: **EYE PROTECTORS !** in the display for about 4 sec. Will remind you to wear the protection goggles.

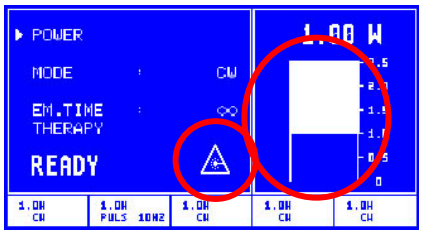
4.9. Activating the Foot Switch

When the aiming beam is visible, the parameters of power and mode are adjusted and the "READY" signed is displayed, the foot-switch is then depressed and held down. The treatment beam is now conveyed through the fiber.

The laser device does not emit the treatment beam if the foot-switch is not activated, but does emit the aiming beam. When the foot-switch is released, the treatment beam is immediately interrupted.

4.10. Warning Display and Noise during Laser Operation

Laser emission is indicated by means of a Laser Sign, which occurs right beneath READY sign on the screen. The bar graph indicating the power will be inverted during laser emission. During the emission the treatment beam a pulsing beep can heard



the

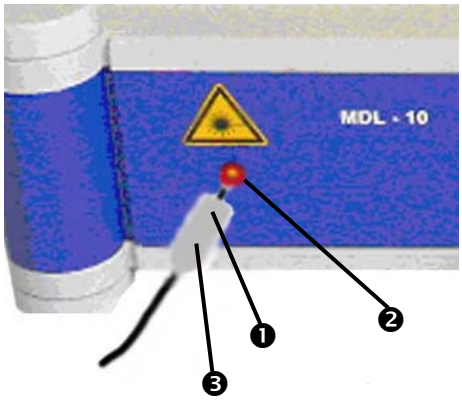
of

be

4.11. Switch Off

To switch off the system, the key switch is turned to the left by 90° to the vertical position. The device is now switched off.
After switching off the laser, the key switch should be removed to control access to the system.

5. Laser Fiber



The laser fiber required when using the VISION laser device MDL-10 is connected to the fiber connector jack at the front of the device. The fiber has a self centering fiber plug /SMA plug)

1. Insert the fiber plug ❶ into the fiber jack ❷
2. Tighten the cap screw ❸ on the fiber plug hand-tight. Be careful not to use excessive force as this could damage the fiber coupling and interfere with transmission of the laser beam.

The aiming beam is emitted at the distal end of the fiber.

To remove the laser fiber, loosen the cap screw and then pull out the plug.

In the VISION laser unit MDL-10, a laser beam is emitted only from the distal end of the connected laser fiber.

⚠ **CAUTION**

Prior to use, the laser fiber must be visually examined by the user and must be in perfect condition. The end of the fiber must have a flat surface without any edge breaks and this surface must be perpendicular to the fiber axis (see Chapter 9.1)

5.1. General Description and Warnings

CAUTION

Laser fibers are made from quartz glass and thus are very fragile and should be treated with care. They can break, especially if bent too much. In that case, the edge where the breakage occurs may be sharp. Personnel handling laser fibers have to be aware of this, receive proper training in the handling of laser fibers, and observe all safety guidelines.

The laser fibers for the VISION laser device MDL-10 are used to transfer the laser energy from the laser to the target. The fiber must either be placed in contact with the tissue be placed in a distance from the tissue to create heat for coagulation or crate energy for chemical reactions. Various fibers with different diameters are provided for use (refer to Chap. 13, technical data, for details)

WARNING

Although the laser fibers are highly flexible, they can be damaged by extreme bending or excessive mechanical stresses. This damage may include tiny faults that are not visible to the naked eye but that can cause the fiber to fracture. If this occurs during the procedure, it could result in complications such as perforation of soft tissue, injuries to mucous membranes, oedema, or bleeding and will require removal of the fiber fragment.

Throughout the entire laser procedure, all personnel including the patient must wear protective laser goggles. This is because there is a risk of uncontrolled emission of laser energy if the fiber should fracture.

Observe the following precautions to avoid the risk of fracturing the laser fibers:

- Always use only original VISION laser fibers for the MDL-10
- Do not bend the fiber excessively
- Do not pull on the fiber or connector.
- Do not use clamps to hold the fiber in place
- Do not place any objects on the fiber
- If there is any sign of damage to the fiber, replace it with a new fiber
- The fiber may not be sterilized in an autoclave
- Remove the protective cap from the SMA connector only if the laser fiber is to be used.
- After use, reattach the protective cap to the SMA connector
- Before attaching the SMA connector make sure that the threading of the SMA connector and the coupling jack are completely clean
- Do not touch storage surfaces or items with the end of the connector or the distal end

5.2. Precautions when using the Fiber with an Endoscope

- Insert the fiber into the endoscope carefully. Never use excessive force.
- Especially when using flexible endoscopes, be careful to avoid excessive stresses to the fiber from flexion. The fiber may not be inserted into the flexed distal end of the endoscope as this could damage the instrument and/or the fiber.
- Before firing the laser, always verify that the fiber projects at least 3 – 5 mm beyond the endoscope and that the distal end of the fiber is visible at all times.
- After the procedure has been completed, the fiber should be removed from the endoscope.

5.3. Structure and Preparation of the Laser Fibers

Fiber structure

The optical fiber consists of the following:

- Inner core – quartz glass fiber
- Optical cladding
- Exterior coating

Preparation of the Distal Fiber End

⚠ **WARNING**

Always wear protective goggles with clear glass when preparing the fiber to prevent injury to the eyes due to glass splinters.

To ensure maximal energy transference with the fiber, it is important that the front ends are broken exactly at a right angle to the fiber axis and that the ends are clean.

If the emission of the fibers is no longer sufficient according to the requirements listed in the manual (Chapter 9.19, the end of the fiber can be newly prepared.

Preparation consists of the definite breaking of the quartz fiber, followed by the mechanical removal of the coatings surrounding the glass fiber.

Breaking the fiber

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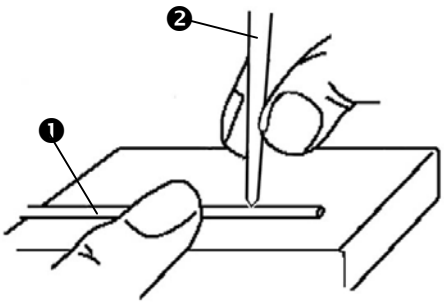
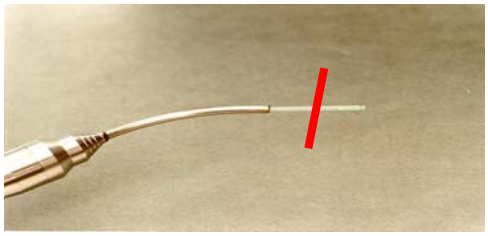
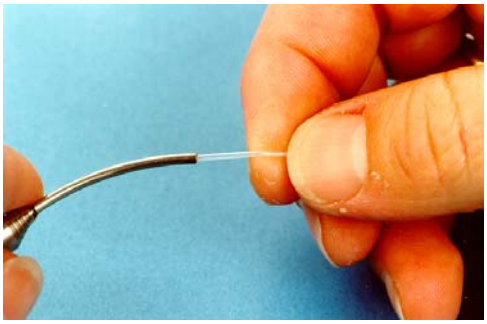


❶ Place the fiber on a flat surface, ideally a silicone plate

❷ With the diamond knife careful cut through the plastic cladding and very careful scribe the quartz glass fiber

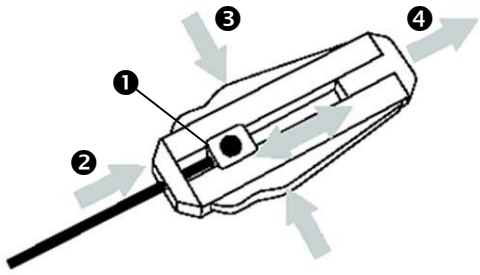


Watch the red aiming beam, which is easy to see exactly at the scribing point.



Bend the fiber at this point and break very softly the quartz core.

Removing the cladding



❶ Set the safety slide of the tool according to the length to be stripped (appr. 3 – 5 mm)

❷ Insert the fiber end into the stripping tool up to the set stop

❸ Pinch the tool

❹ Keep the tool pressed together and strip the coating from the fiber

Sterilization of the Accessories

Fiber stripping tool and diamond knife may be sterilized in ETO.

6. Safety Functions

6.1. Warning Equipment during Laser Emission

The VISION laser device MDL-10 is equipped with an optical signal that indicates that laser radiation is being emitted. This optical signal is a LASER EMISSION SIGN, appearing on the screen right beneath the READY sign. Simultaneous the bar graph of set power will invert.

6.2. Safety Components

To guarantee operational safety in medical use, the VISION laser device MDL-10 contains a number of supplementary safety features to prevent malfunction.

Emergency STOP switch

On the front side of the device, there is a red emergency STOP switch that disconnects the device completely from the power supply when it is oppressed. The restart the device, gently pull the emergency STOP switch.

Key Switch

In order to enable the operator of the VISION laser device MDL-10 to control access to it, the device can be started only by using a key for the key switch on front of the device. The key can be removed only after the laser is turned off. The key must be kept in a safe place so that only authorized persons can operate the laser.

Foot Switch

The laser can be operated only by using the installed foot switch. Laser emission occurs only when the foot switch is depressed. When the foot switch is released, laser emission is immediately interrupted. To avoid inadvertent laser emission, the foot switch is provided with a protective cover.

Automatic Monitoring of the Emitted Laser Power

The laser power emitted is constantly monitored automatically by the device. In unacceptable deviations occur, laser emission is automatically interrupted.

Safety lock

In case of failure or emergency stop an electronic feedback controlled safety lock blocks the laser emission. The function of this safety lock as well as its current state (active or non-active) are constantly monitored automatically. Any fault condition will result in the immediate shut down of the laser.

Aiming beam

An aiming beam is incorporated into the fiber to direct the fiber to its target and control the laser fiber. This beam is visible as a red light at the end of the fiber and presents no danger with respect to its power output. The laser may not be operated if the aiming beam is not visible.

Cooling

The laser cooling has its own state controls, which affect the safety circuit. In case of a fault, the device is returned to a safe state immediately so that the device is not allowed to overheat.

6.3. Access Control

The user must ensure that the VISION laser device MDL-10 is protected against access by unauthorized persons when it is not being used by removing the key.

6.4. Safety related accessories

Only fibers recommended by VISION may be used with this laser. The use of fiber systems made by other manufacturers together with the VISION laser device MDL-10 will lead to unknown results and will void any warranty on the part of VISION. The foot switch is also a safety related item. All accessories are included with the laser device and replacement parts must be obtained from VISION or from an authorized dealer of VISION.

6.5. Safety Inspections

Safety inspections must be performed at regular intervals, and no more than 12 months apart. The inspections must be performed by persons authorized by VISION. The type and scope of checks are prescribed and carried out by VISION technicians or persons authorized by VISION only.

7. User Menu

A user menu for dental applications is separately available.

8. Options

No options are available for this device.

9. Function Test

WARNING

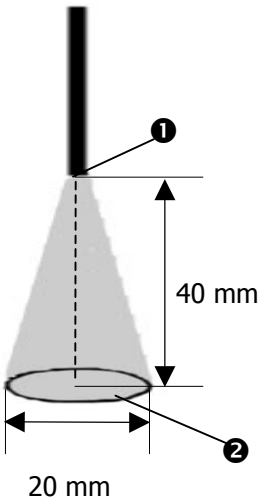
The function test must be performed prior to each operation.

Check all the disposable items before removing them from the package to ensure that the package is intact and that the expiration date has not been passed.

Use only the original accessories for your own and the patients safety.

9.1. Inspecting the laser fiber

prior to use, the laser fiber must be visually inspected by the user to verify that it is in perfect condition. This is done with the help of the aiming beam as follows:



In the standby mode with treatment beam shut off and the aiming beam turned on, the end of the fiber ❶ is directed onto a bright surface. This will allow the characteristics of the aiming beam emitted from the fiber to be easily observed. The area illuminated by the aiming beam must for a circular surface ❷ of homogeneous illumination with a diameter of approximately 15 mm, when it is approximately 50 mm away from the end of the fiber ❶. The light circle must be centered on the extension of the longitudinal fiber axis and exhibit a sharp edge.

WARNING

Laser fibers that do not pass the direct visual check and the above aiming beam test must not be used.

The function test is complete. The device is tested and ready to be used in the operating room.

WARNING

Never use the device if it has obvious defects, especially if these involve the power plug or the power supply connection cables. Have the device repaired by VISION technicians or persons authorized by VISION only.

NOTE

After preparation, the aiming beam must be perfectly round as described in section 9.1. An irregular shape can be a sign of a damaged fiber. In this case, the fiber may not be used. Failure to observe this note can lead to undesired treatment results and damage to other accessories.

Perform a functions test prior to the beginning of operation.

10. Operating the laser

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Prior to operation:

- Turn the device on.
- Connect the laser fiber.
- Connect the foot switch and interlock.

10.1. Aiming beam

The point of incidence of laser radiation is indicated optically by the aiming beam that emits from the distal end of the laser fiber, as does the treatment beam.

The aiming beam assists the operator in targeting for the purposes of positioning the fiber in contact with the tissue to be treated. It also aids in checking the integrity of the fiber.

10.2. Adjusting Mode, Power and other Parameters

The Mode, the output power and other parameters can be adjusted using the operators panel and related buttons.

All values can only be adjusted when the foot switch is not activated.

10.3. Use of the Device

Insert the end of the fiber, after it is ready for use, into the working instrument (hand piece, endoscope etc) and push forward until the end of the fiber with the aiming beam is visible either at the distal end of the hand piece or in the endoscopic picture.

Maneuver the hand piece or endoscope with the laser fiber until the end of the fiber is in direct contact to the tissue (for cutting), is in a distance of a few mm to the tissue (for coagulation), is in a distance of a few cm and low power output (for bleaching and therapy).

Switch the laser into ready mode and depress the foot switch. Continue until the desired effect has been achieved.

⚠ **DANGER**

The emission of the laser energy must be interrupted as soon as the field of view (direct or by endoscope) is unclear due to blood and residuals from the laser impact. Treatment may continue only after the view of the surgical site has been fully restored.

DANGER

The distal tip of the fiber must be monitored constantly, under direct or video-aided vision, both during use and while the fiber is being advanced or withdrawn.

10.4. Replacing the fiber

A sterile fiber should be used with every patient for reason of hygiene. Replace the entire fiber by removing the SMA connector and connecting a new laser fiber. Proceed as described under Chapter 5.

10.5. Trimming the Laser Fiber during the Procedure

If it should become necessary to trim the laser fiber during the procedure, proceed according to the following steps und sterile conditions:

1. Switch the laser into standby mode
2. Withdraw the laser fiber from the hand piece/endoscope
3. Score the fiber using the diamond knife supplied and break the fiber
4. Strip the required length of insulation from the fiber. Use the proper stripping tool for the fiber type.

WARNING

Wear protective eyeglasses when stripping the fiber.

After preparing the fiber, examine the fiber as described in Chapter 9.1

10.6. Possible Hazards resulting from improper Operation

If the device has been started properly and the laser fiber test has been performed with positive results, the laser radiation can only be emitted from the distal end of the laser fiber. The only possible operational error in this case would be if the end of the fiber were directed to non-targeted tissue and the laser radiation were initiated by activating the foot switch. This may result in unwanted damage of non-targeted tissue.

Also, the user could operate the device without visual contact with the end of the fiber or without seeing the aiming beam. This can result in undesired impact and damage of non-targeted tissue.

If the aiming beam cannot be seen when the laser is turned on and the laser fiber is inserted, the working fiber may be broken. Activating the treatment beam can then result in undesired uncontrolled radiation in the operating room or in the working channel of the hand piece or endoscope. This may cause personal injury or damage to the hand piece or endoscope.

DANGER

Failure to observe the basic safety rules specified in laser safety regulations (such as not wearing protective eyewear or unauthorized entry into the laser area) is not permitted.

DANGER

The laser beam may be directed only at targeted tissue. Use of the laser beam for any other purpose or allowing it to radiate freely within the treatment room can result in injury to the patient, the operating team or a third party.

11. Service and Maintenance

To preserve the device and ensure its proper function, proper service, maintenance and storage must be provided for.

11.1. Cleaning the Device

⚠ **WARNING**

Prior to cleaning: Turn off the device.

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1. Switch the device off at the key switch
2. Remove the power cable
3. Wipe the surfaces of the device and the foot switch with a cloth moistened with disinfectant. The concentration of the disinfectant should be according to the information provided by the disinfectant manufacturer. Penetration of fluid into the device must be avoided. Avoid splashing water on the device.

The device must be cleaned, but only from the outside. All components located inside the housing must be serviced only by a service technician authorized by VISION.

For disinfectant purposes, common cloth disinfectants must be used. Spray disinfectants entail a risk of the media finding its way into the openings of the device. Therefore, never use a spray disinfectant. In particular, care must be taken that no fluids find their way into the fiber jack. Surface disinfectants include these products:

Incidur®/Henkel
Minutil®/Henkel
Incidin® plus/Henkel
Incidion® perfect/Henkel
Helipur®/Braun

⚠ **WARNING**

Prior to turning on the device: wait for the surfaces of the device to be dry.

⚠ **CAUTION**

Do not sterilize the device !

11.2. Cleaning the Laser Fiber

WARNING

Laser fibers for the MDL-10 are disposable products and as such may not be reused. Check expiration/storage date. Do not use after expiration date.

For hygiene purposes, a sterile fiber system must be used for each patient.

If a distal end of a laser fiber is cut back during an operation, a suitable fiber preparation device must be used to guarantee acceptable quality of the distal end of the fiber (see Chapter 10.5.)

Prior to using the reworked fiber, its quality must be examined as described in Chapter 9.1.

The laser fiber does not need to be cleaned as it is a disposable product. If it is defective, it must be replaced by another intact laser fiber. For checks of the laser fiber by the user, see Chapter 9.1.

11.3. Maintenance

WARNING

Do not open the device. The device may not be serviced or adjusted by the user. Only authorized service technicians may perform repairs, adjustments or alterations to the device.

WARNING

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

12. Annual Inspection

12.1. Safety Inspections

Safety inspections must be performed at regular intervals, and no more than 12 months apart, by VISION or by service personnel authorized by VISION.

The individual test items must be checked off on a test form. Measurement results and any faults must be noted on the test form.

The test form must be signed by the inspector and countersigned by a representative of the user. A copy of the test form remains with the user.

⚠ **DANGER**

If one of more safety-related points contain faults after the safety system check are done, the device should not be used.

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13. Technical Data

laser source:	(GaAl) gallium – aluminium – laser diode - directly fiber coupled
power:	0,01 – 2,5 Watt
pulse duration:	0,5 ms - 1 sec.
wavelength:	980 nm ± 10 nm
beam divergence:	> 40°
laser class:	4
pilot beam laser class:	laser class 1
environmental temperature during operation:	18 – 30 °C
storage temperature:	- 10 to + 40 °C
Relative Air Humidity:	< 90%
power supply:	110/220 V ac, 50/60 Hz
power consumption:	max 1,0 A
medical class of the device:	class II b
dimensions, weight:	210 x 230 x 300 mm, 4,7 kg
Manufactured and tested	IEC 601-1, 601-2-22
EMC	IEC 601-1-2

Instruments for application

- fused silica fibers with polyamide hard cladding

titanium hand pieces:	200 µm	600 µm

14. Accessories

order No.	Items
MDL-10.010	Titanium hand piece
MDL-00.102	Laser fiber 200 µm, 2.0 m long with SMA connector
MDL-00.106	Laser fiber 600 µm, 2.0 m long with SMA connector
MDL-00.103	Laser fiber 300 µm, 2.0 m long with SMA connector
MDL-00.104	Laser fiber 400 µm, 2.0 m long with SMA connector
MDL-00.800	Bleaching hand piece
MDL-00.701	Laser safety eyewear 985/L4 type Full View
MDL-00.702	Laser safety eyewear 985/L4 type Goggle
MDL-00.500	Diamond knife
MDL-00.400	Fiber stripping tool, adjustable for 200 – 600 µm
MDL-00.910	Short circuit plug for door contact
MDL-00.001	Mains supply cord, Europe 2.5 m
MDL-00.920	Foot switch with connecting cable and plug
MDL-00.990	Cart

Original accessories: For your own safety and that of your patient, use only original accessories.

15. Troubleshooting Instructions

See TROUBLE SHOOTING MANUAL

16. Test Record

Date	Output test [W], Programs	Remark	Stamp/Signature